UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge

MANUFACTURER DEFENDANTS' OMNIBUS BRIEF IN SUPPORT OF MOTION TO QUASH AND FOR PROTECTIVE ORDER REGARDING PLAINTIFFS' SUBPOENAS DIRECTED TO THIRD PARTIES

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INTRODUCTION

This case concerns an alleged impurity in valsartan that purportedly occurred due to a chemical reaction in the manufacture of the active pharmaceutical ingredient. Notwithstanding the specificity of Plaintiffs' claim, they have received millions of pages of documents in response to approximately 140 total document requests from more than a dozen Defendants covering the entire valsartan supply chain. This discovery has required months and months of intensive labor by hundreds of attorneys and contract attorneys, at an expense easily in the tens of millions of dollars. Notwithstanding the massive amount of information produced by the parties with regard to the specific chemical reaction at issue, Plaintiffs seek even more information on this issue via 75 subpoenas directed to third parties (the "Third Parties").

It simply strains credibility to imagine any third party may have in their possession information that is ***material*** to Plaintiffs' claim and has not already been produced by Defendants. Yet, rather than identify third parties based on a particular need for such specific information, the Plaintiffs' Third Party subpoenas (the "Subpoenas"), all of which were improperly served and the vast majority of which exceed the Court's subpoena power, contain more than 45 separate document requests covering 11 categories of information corresponding to the same categories of information Plaintiffs have sought from Defendants. Moreover, Plaintiffs served

virtually identical subpoenas on all of the third parties, notwithstanding the myriad differences in their businesses, their geographical locales, and each entity's specific relation, if any, to this case. Plaintiffs' sweeping subpoenas flout this Court's previous admonitions about overbroad and boilerplate discovery, and seek information that is irrelevant and disproportionate to the needs of this case, and that exceeds the scope of the Court's previous rulings concerning the parameters of discovery in this action.

For these reasons, as discussed more fully below, Defendants[1] request the Subpoenas attached at Exhibit A be quashed, and, in the alternative, that the Subpoenas identified at Exhibit B be quashed in their entirety and Plaintiffs be directed to narrow the scope of the Subpoenas identified at Exhibit C.[2]

FACTUAL AND PROCEDURAL BACKGROUND

I. The Improperly Served and Overbroad Subpoenas

On September 17, 2020, the Court ordered Plaintiffs to identify "the entities

[1] Defendant Hetero Labs has indicated that it does not wish to join in the instant Omnibus Brief and will pursue relief, if any, with regard to the subpoenas directed toward third party entities purportedly affiliated with Hetero Labs by way of a separate motion. The Subpoenas served on Third Parties purportedly related to Hetero are excluded from Defendants' Motion.

[2] Defendants note that, in accordance with the Federal Rules of Civil Procedure, all Third Parties have the right to provide their own responses and objections to their respective subpoenas, and nothing in this submission should be interpreted to in any way waive, hinder, or limit those rights of the Third Parties.

they intend to serve with third-party document subpoenas" by September 30, 2020 and to effect service by October 15, 2020. *See* Dkt. 575 at ¶ 3. On September 30, 2020, Plaintiffs sent Defendants a list of Third Parties they intended to subpoena, and invited Defendants to meet and confer about those entities. *See* **Ex. D.** Email from Goldenberg, 9-30-20. In response to that email, Defendants requested copies of the subpoenas or lists of the information Plaintiffs intended to request. *See* **Ex. E**, Email from Goldberg, 10-2-20, ("Counsel for ZHP and Solco also would like to have a call, and it would be helpful to see the draft subpoenas or the list of information you are seeking from the Third Parties in advance of the call."). However, Plaintiffs refused to provide that information unless all of the Defendants agreed to accept service of all of the Subpoenas. *See* **Ex. E**, Email from Goldenberg, 10-2-20 ("Will Defendants first inform Plaintiffs for which entities they will agree to accept service or process?"). After this exchange, and without first providing copies of the subpoenas or lists of the categories of documents to be requested, Plaintiffs purported to serve the 75 Subpoenas on October 15 and October 16, 2020. *See* **Ex. F.**

Notwithstanding that the 75 Subpoenas are directed to myriad types of entities, including vendors, manufacturers, raw ingredient suppliers, re-labelers, repackagers, testing consultants, and recall service providers, many of whom are

foreign entities that exist and operate outside of the United States,[3] each Subpoena seeks virtually identical categories of information via more than 45 document requests: (1) Corporate Organization; (2) Contracts; (3) Communications with relevant parties; (4) ANDA and DMF file documents; (5) Nitrosamine Contamination; (6) Recall Related Documents; (7) Quarantine and/or Destruction of products; (8) Communications with the FDA; (9) Testing Data; (10) Solvent Manufacturing, Recovery, and Recycling; and (11) Toxicology Assessments. *See, e.g.*, **Exs. A-9, A-47, and A-35,** Subpoenas directed to CABB AG (raw material supplier), Return Logistics (recall provider), and Malvern Instruments (supplier of particle size testing equipment).

By way of example, the Subpoenas directed to CABB AG, a supplier of raw materials, and Malvern Instruments, a provider of equipment used to test particle size, contain the exact same categories of requests with nearly identical topics within those categories. *Compare* **Ex. A-9** *with* **Ex. A-35.** These identical categories of requests contain demands for documents related to topics totally outside the realm of the services these entities perform, namely, Recall-Related Documents, Quarantine/Destruction of products, Communications with the FDA, and Toxicology Assessments. *Id.* These same categories and topics of document requests

[3] For example, the Subpoenas directed to Third Parties allegedly related to ZHP in and of themselves include entities located in Canada, China, Germany, India, Spain, Switzerland, and the United Kingdom.

are also included in the Subpoena to Tiefenbacher API + Ingredients, a German customer who purchases APIs exclusively in Europe, and in the Subpoena to Return Logistics International, Inc., a company that provides recall return services in the United States. *See* **Exs. A-59, A-47**. This pattern of overlapping, duplicative, and unrelated categories of requests persists throughout all of the Subpoenas.

II. Plaintiffs' Refusal to Narrow or Withdraw the Subpoenas

Among the Orders entered by the Court in these proceedings, two are particularly pertinent to the Subpoenas: the Macro Discovery Order and the Confidentiality and Protective Order.

The Macro Discovery Order (Dkt. 303) was entered on November 26, 2019, and limits discovery in the following pertinent ways:

> Plaintiffs' request for discovery regarding other products using the same manufacturing processes, solvents, and testing as those for Valsartan API is DENIED. However, defendants shall produce all documents reflecting the presence of any nitrosamine in any sartan product.
>
> *****
>
> Plaintiffs' request for foreign sales, marketing materials and agreements is DENIED. However, to the extent defendants are in possession, custody, or control of documents from any source regarding unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan, the documents shall be produced.
>
> *****

> […] Plaintiffs are also entitled to discovery regarding any test that could identify the presence of nitrosamine contamination. Also, testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the Valsartan API and Valsartan are relevant.

Dkt. 303 at ¶¶ 4, 7, 8.

The "Protective Order" that governs the production of documents in this action, including by third parties. Dkt. 139, ¶ 2 ("[t]hird parties may avail themselves of, and agree to be bound by, the terms and conditions of this protective Order and therefore become a Producing Party and/or Receiving Party for purposes of this Protective Order."). The Protective Order mandates that "[d]ocuments produced by a non-party must be treated by the receiving party as PROTECTED INFORMATION for a period of fourteen (14) days from receipt. *Id.* at ¶ 14. Also contained within ¶ 14 is the express grant that each party has the right to designate PROTECTED INFORMATION produced by Third Parties within fourteen (14) days of receipt of the third-party documents. *Id.*

Given their restrictions on discovery in this litigation, the Macro Discovery Order and the Protective Order require the Subpoenas be narrowed. Accordingly, pursuant to their "meet and confer" obligations as set forth in Local Rule 37.1(a)(1), Defendants each separately met with Plaintiffs during which Defendants proposed the narrowing or withdraw of the Subpoenas. Despite the glaring overbreadth of the Subpoenas' "one size fits all" approach, the clear restrictions set forth in the Macro

Discovery Order and the Protective Order, and the rules regarding the discovery of relevant information, Plaintiffs refused to withdraw any of the Subpoenas prior to the Case Management Conference on Wednesday, November 11, 2020, and agreed to narrow just two Subpoenas. Accordingly, Defendants were forced to raise their objections to the Subpoena in their letter brief dated November 9, 2020, which included, *inter alia*, improper notice, the overbreadth and irrelevancy of the requests, and defiance of the Macro Discovery and Confidentiality Orders directives.[4]

So that the Court could resolve Defendants' objections to the Subpoenas, as well as those of any of the Third Parties, the Court ordered this Omnibus Brief:

> All motions for protective orders addressing plaintiffs' third-party subpoenas shall be filed no later than December 4, 2020. Defendants' shall file an omnibus motion that addresses issues and disputes common to all defendants. Defendants may file separate motions that address issues specific to them. Responses shall be filed by December 31, 2020. Replies may be served by January 8, 2021. Oral argument regarding the motions will be held during the January 13, 2021 scheduled conference call. These scheduling deadlines apply to parties and non-parties. Plaintiffs' counsel shall notify and serve the third-parties with a copy of this Order.

Nov. 13, 2020 Order (Dkt. 629) at ¶ 4.

Since the Case Management Conference on November 11, 2020, Defendants

[4] Prior to the November 9, 2020 Letter Brief submitted by Defendants Aurobindo (joined by Torrent) and Teva filed Motions to Quash, and Mylan served written Objections to their respective Subpoenas.

have continued to pursue the withdrawal or narrowing of the Subpoenas with minimal success. After multiple meet and confer sessions with each Defendant, the only Subpoena Plaintiffs withdrew was a Subpoena that contained 57 separate document requests issued to an attorney at Duane Morris who is a member of the group of attorneys currently representing ZHP in this litigation. And Plaintiffs only agreed to withdraw this patently overbroad and unnecessary Subpoena after counsel for Duane Morris provided Plaintiffs with a sworn affidavit from the subpoenaed attorney repeating the representations made to Plaintiff throughout the entire meet and confer process.

III. Status of Third Party Responses and Objections

To date, Plaintiffs have apparently served 49 subpoenas[5], and have received written objections and responses from at least eight Third Parties and documents from three Third Parties. *See* **Ex. [ ]** Email from Stellpflug, 12-3-20. Another five Third Parties informed Plaintiff that they have no responsive documents or information. *Id.* At this moment, it appears nearly half of the Third Parties have not been served and, after several meet and confers, Plaintiffs have not indicated when they intend, if ever, to formally serve the foreign Third Parties by way of the Hague

[5] Based on the 49 affidavits of service provided to Defendants, it appears Plaintiffs have attempted service on several third parties more than once by way of different corporate recipients and registered agents. Accordingly, the number of Subpoenas served does not correspond to the number of third parties served.

Convention on the Taking of Evidence Abroad (the "Hague Convention").

But, the unreasonable burden and overbreadth of the Subpoenas is made clear even in the responses of the Third Parties who did serve written responses and objections. *See* **Ex. H.** Counsel for one Third Party wrote to Plaintiffs expressing how "troubled [they were] by the breadth and scope of the subpoena". *See* **Ex. H-1.** Letter from Schmitt, 11-9-20. Another Third Party wrote to Plaintiffs stating that there was "no relationship with any defendant that would justify 46 wide-ranging document requests" and pointed out that, upon reviewing the docket for themselves, they emphasized that "Plaintiffs have served the same one-size-fits-all subpoena upon 28 entities." *See* **Ex. H-2**, Letter from McMinn, 11-9-20.

ARGUMENT

At issue in this Omnibus Motion is whether (i) all of the Subpoenas should be quashed due to improper notice and service, (ii) 32 subpoenas should be quashed on relevance grounds, especially given the Macro Discovery Order, and (iii) all non-quashed subpoenas should be narrowed consistent with the rules of relevance, the Macro Discovery Order, and the Protective Order.

I. Defendants Have Standing to Quash or Modify Plaintiffs' Third Party Subpoenas

"A party to the action will have standing to quash or modify a non-party subpoena when it claims a privilege or privacy interest in the information sought from the nonparty." *Schmulovich v. 1161 Rt. 9 LLC*, 2007 WL 2362598, at *2

(D.N.J. Aug. 15, 2007). Furthermore, this Court has held that it "does not accept the notion that a party can subpoena irrelevant documents in a case with impunity," and that "[t]here is authority for the position that a party can move for a protective order in regard to a subpoena issued to a non-party which seeks irrelevant information." *Costantino v. City of Atl. City,* 2015 WL 12806490, at *3 (D.N.J. Nov. 4, 2015) (rejecting argument that party lacked standing to quash subpoena to third party), *see also In re REMEC, Inc. Securities Litigation*, 2008WL 2282647, at *1 (S.D. Cal. 2008) ("[a] party can move for a protective order in regard to a subpoena issued to a non-party if it believes its own interests are jeopardized by discovery sought from a third party and has standing under Rule 26(c) to seek a protective order regarding subpoenas issued to nonparties which seek irrelevant information"); *Washington v. Thurgood Marshall Academy,* 230 F.R.D. 18, 22 (D.D.C. 2005) (a party has standing to move for a protective order if a third-party subpoena seeks irrelevant information).

Here, the Subpoenas seek irrelevant information and Defendants, therefore, have standing to quash those Subpoenas or to seek a protective order limiting their scope. In addition, the Subpoenas are so broad that they encompass information protected by the provisions of the Protective Order as well as the attorney-client privilege and the work product doctrine. Therefore, because Defendants have a privilege and a privacy interest in the information sought from the Third Parties, they have standing upon which to move to quash and/or modify the Subpoenas.

II. Plaintiffs' Third Party Subpoenas Violate Rule 45

In serving the Subpoenas, Plaintiffs have ignored the requirements of Federal Rule of Civil Procedure 45 regarding notice, geographic limits, and territorial scope. As a result of these fundamental procedural defects, the Subpoenas are void and unenforceable and should be quashed.

A. Plaintiffs Failed to Provide the Required Notice

As a threshold matter, all of Plaintiffs' third party subpoenas, including both those directed domestic entities and those directed to foreign entities, are invalid because Plaintiffs ignored Rule 45's prior notice requirement. Specifically, Rule 45 mandates that "[i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then ***before it is served on the person to whom it is directed***, ***a notice and a copy of the subpoena must be served on each party***." FED. R. CIV. P. 45(a)(4) (emphasis added). Although Plaintiffs assert that Defendants have no procedural right to object to these subpoenas, the prior notice requirement exists to allow all parties to the litigation the opportunity to object before documents are produced:

> A party issuing a subpoena to a non-party for the production of documents during discovery must provide prior notice to all parties to the litigation. The term "prior notice" means notice prior to service of the subpoena on the non-party, rather than prior to document production. ***The purpose of prior notice is to afford other parties an opportunity to object to the production or inspection*** and

> to obtain the materials at the same time as the party who served the subpoena.

Coleman-Hill v. Governor Mifflin Sch. Dist., 271 F.R.D. 549, 552 (E.D. Pa. 2010) (citations omitted) (emphasis added).

Here, Plaintiffs failed to serve Defendants with copies of the Subpoenas prior to initiating service on the third parties. Instead, Plaintiffs have admitted that the subpoenas were "in the process of being served on the [non-]parties identified therein" at the time Plaintiffs first sent copies of the subpoenas to Defendants. (*See* **Ex. F**, 10-16-20 email serving subpoenas.) Likewise, the Subpoenas themselves indicate that they were served on third parties the day before Plaintiffs provided copies of the Subpoenas to Defendants. *See, e.g.*, **Ex. A**-1 at 1. Prior to service of the Subpoenas, Plaintiffs identified only a list of entities to that Plaintiffs intended to subpoena. Plaintiffs did not, however, communicate any of the specific requests for documents and information that were ultimately incorporated into the Subpoenas, despite Defendants' specific request for this information.

Plaintiffs' deliberate failure to provide proper notice directly violates Rule 45, and renders the Subpoenas void and unenforceable. *See, e.g.*, *Fla. Media, Inc. v. World Publ'ns, LLC*, 236 F.R.D. 693, 695 (M.D. Fla. 2006) (finding subpoenas issued to 80 non-parties void and unenforceable where the plaintiff failed to give prior notice to the defendant); *Coleman-Hill*, 271 F.R.D. at 555-56 (admonishing plaintiff's counsel for failing to serve copies of non-party subpoenas ***before*** serving

them on third-parties, which would have afforded "the opportunity to lodge objections."). As a result, the Subpoenas are invalid and should be quashed.

B. The Subpoenas Exceed the Geographic Limits of Rule 45

Rule 45 provides that a subpoena may command the "production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person." FED. R. CIV. P. 45(c)(2)(A). ***All but one***[6] of the domestic Third Parties are located more than 100 miles from Plaintiffs' designated place of compliance at 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401. The same is also true for the foreign entities Plaintiffs have identified.

It is well-settled that "a subpoena that purports to compel production beyond the geographical limits specified in Rule 45(c) does not comply with the requirements of the Rule." *Uniloc USA, Inc. v. Apple Inc.*, 2020 WL 6262349, at *2 (N.D. Cal. Oct. 23, 2020) (denying Apple's motion to compel compliance with non-party subpoena). Therefore, because the Subpoenas seek to compel compliance at a location more than 100 miles from where these entities are headquartered, the Subpoenas are facially invalid and unenforceable. *See AngioScore, Inc. v. TriReme Med., Inc.*, 2014 WL 6706873, at *1 & n.1 (N.D. Cal. Nov. 25, 2014) (holding that

[6] Axis Clinicals (Mylan) is within 100 miles of the place of production.

a Rule 45 subpoena specifying the place of compliance as more than 100 miles from nonparty's headquarters was "invalid on its face"). This Court should quash each of the Subpoenas on this basis.

C. The Subpoenas are Improper and Invalid as to Foreign Third Parties

The Subpoenas issued overseas to foreign Third Parties are invalid because, as foreign entities who are non-parties to a case, the foreign Third Parties are beyond the jurisdiction of a United States District Court's subpoena power. *See, e.g.*, *Viasat, Inc. v. Space Sys./Loral, LLC*, 2014 WL 12577593, at *5 (S.D. Cal. June 30, 2014) (concluding that a non-party Canadian company "is not a United States national or resident and therefore cannot be served with a subpoena under Rule 45."); *Litetronics Int'l Inc. v. Technical Consumer Prods., Inc.*, 2006 WL 2850514, at *2 (N.D. Ill. Sep. 28, 2006) (noting that a Chinese corporation is beyond the jurisdiction and subpoena power of the Court and suggesting that the parties investigate whether the Hague Convention would be an appropriate means of service). This Court has likewise acknowledged that its subpoena power does not permit it to compel discovery of non-party foreign entities. *See In re: Benicar (Olmesartan) Prod. Liab. Litig.*, 2016 WL 5817262, at *3, n.13 (D.N.J. Oct. 4, 2016) (recognizing that "Rule 45 does not authorize the service of a subpoena on a foreign witness[,]" and that "[t]he scope of Rule 45 is limited to service in the United States or service of a subpoena on a United States national or resident in a foreign country.").

Furthermore, many of these entities are located in countries, such as India and Germany, that are signatories to the Hague Convention.[7] Thus, discovery is available to Plaintiffs via the Hague Convention and must be obtained in accordance therewith. *See GMA Accessories, Inc. v. Solnicki*, 2010 WL 3749213, at *1 (S.D.N.Y. Sept. 24, 2010) (finding subpoena to non-party was not properly served, and stating that "[t]he Hague Convention's procedures for service are mandatory here because Argentina, the country in which [the plaintiff] sought to serve the subpoena on [the non-party], is a signatory to that Convention.").

To date, Plaintiffs have made no attempt to avail themselves of the Hague Convention with respect to service of the Subpoenas.[8] Further, to the extent

[7] *See* Hague Conference, The Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Mar. 18, 1970, available at https://www.hcch.net/en/instruments/conventions/full-text/?cid=82 (last accessed November 30, 2020).

[8] In fact, rather than attempt proper service on foreign Third Parties under the Hague Convention, Plaintiffs simply demanded that Defendants accept service and produce documents on the foreign entities' behalf. *See* Dkt 618 at pp. 4-5. The Court should swiftly dispose of Plaintiffs' request because a party is not obligated to produce documents that it does not possess or cannot obtain. *Princeton Digital Image Corp. v. Konami Digital Entertainment Inc.,* 316 F.R.D. 89 (D. Del. 2016); *see also Eisenband v. Pine Belt Auto., Inc*., 2020 WL 1486045, at *8 (D.N.J. Mar. 27, 2020) (awarding Defendant summary judgment because Plaintiffs could not show that Defendant had control over third party's documents). First, in order to compel Defendants to accept service on behalf of the foreign Third Parties, Plaintiffs must show that Defendants have the authority to do so. *See Laffey v. Plousis,* , 2008 WL 305289, at *5 (D.N.J. Feb. 1, 2008), *aff'd,* 364 F. App'x 791 (3d Cir. 2010) (holding service improper even though fellow employee at defendant's office said he was authorized to accept service, since apparent authority to accept service must be created by acts of the principal – not the agent). Plaintiffs have not shown that any

Plaintiffs assert that effectuating service under the Hague Convention will be time-consuming and may inhibit Plaintiffs' ability to quickly obtain documents, this Court should recall Plaintiffs learned the identities of many of the subject third parties nearly eighteen (18) months ago during the core discovery phase of this litigation. Thus, even if this Court's subpoena power extended to the non-party foreign entities – which it does not – Plaintiffs cannot demonstrate good cause to circumvent the Hague Convention due to Plaintiffs' lack of diligence in attempting to obtain this discovery. Accordingly, this Court should quash the Subpoenas on the foreign entities, identified at Exhibit A, and require Plaintiffs to comply with the Hague Convention.

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of the foreign Third Parties have granted any Defendant such authority. Second, Plaintiffs' argument that the foreign Third Parties' documents are somehow within Defendants' possession, custody and control and therefore Defendants must obtain and produce those documents is equally misguided. The standard to establish a party' possession, custody and control over a third party's documents is not merely that the third party was hired to perform work for the party, as Plaintiffs claim in their Joint Letter Brief. *See* Dkt. 618 at pp. 4-5. Rather, a party must have a contractual right to request and obtain documents from a third Party as evidenced by specific language in a governing agreement between the party and the third party. *Eisenband,* 2020 WL 1486045, at *8. Regardless, even if Plaintiffs could demonstrate that Defendants had possession, custody and control over the foreign Third Parties' documents, that is not the applicable standard by which to determine whether Defendants must accept service on behalf of the foreign Third Parties as it still does not show that the foreign Third Parties granted Defendants the authority to accept service of the Subpoenas on their behalf.

III. The Subpoenas are Overbroad and Seek Discovery that is Irrelevant, Disproportionate, and Beyond the Scope of the Court's Macro Discovery Order

A. The Subpoenas Exceed the Scope of Discovery Permitted By Rule 26

Federal Rule of Civil Procedure 26(b)(1) defines the outer bounds of permissible discovery:

> Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and ***proportional to the needs of the case***, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

FED. R. CIV. P. 26(b)(1) (emphasis added).

Third party subpoenas issued pursuant to Federal Rule of Civil Procedure 45 are subject to the limitation of Rule 26. *Costantino*, 2015 WL 12806490 at *3 (D.N.J. Nov. 4, 2015), (citing *Wahoo Int'l, Inc. v. Phix Doctor, Inc.*, (BLM), 2014 WL 3573400, at *2 (S.D. Ca. July 18, 2014)). Parties are not be permitted to subpoena irrelevant documents in a case with impunity. *Id.* at *3.

The Third Parties are comprised of vendors, manufacturers, raw ingredient suppliers, re-labelers, repackagers, testing consultants, and recall service providers. Despite the obvious and vast differences in the types of entities that were

subpoenaed, each Subpoena[9] seeks virtually identical categories of information via more than 45 document requests: (1) Corporate Organization; (2) Contracts; (3) Communications with relevant parties; (4) ANDA and DMF file documents; (5) Nitrosamine Contamination; (6) Recall Related Documents; (7) Quarantine and/or Destruction of products; (8) Communications with the FDA; (9) Testing Data; (10) Solvent Manufacturing, Recovery, and Recycling; and (11) Toxicology Assessments. *See* **Ex. A**. Most, if not all of these aforementioned categories are included in nearly every Subpoena to every entity, irrespective of function that entity served. For example, there is no defensible reason why a third party supplier of a raw material starting ingredient should have received a subpoena requesting information and documents concerning Recall-Related Documents and Quarantine and/or Destruction categories. *See* **Ex. A-9**, CABB Subpoena. The overbreadth of the Subpoenas, which requires the Third Parties to provide information that has nothing to do with any of the facts or circumstances relating to any of the claims or defenses asserted in this litigation, plainly reaches beyond the requests for relevant information proportionate to the case permissible under Rule 26.

[9] Note that by agreement, the Plaintiffs have narrowed the subpoenas directed to Drs. Charles Wang and Zi Qiang Gu to eliminate most requests related to wholly irrelevant topics.

B. The Subpoenas Exceed the Scope of Discovery Permitted By the Court's Macro Discovery Order

In addition to flouting the limitations on discovery articulated by Rule 26, the Subpoenas include sweeping requests for documents and communications the reach far beyond the scope of the Court's Macro Discovery Order. Dkt. No. 303. The Macro Discovery Order is the law of this case and should be followed. *See, e.g., Musacchio v. United States,* 136 S. Ct. 709, 716, 193 L. Ed. 2d 639 (2016) (law of the case doctrine generally provides that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case); *Krys v. Aaron*, 106 F. Supp. 3d 472, 480 (D.N.J. 2015). Where the Court has made a prior ruling limiting discovery among the parties, that ruling should also be applied to limit the scope of subpoenas issued in the same litigation. *See, e.g., Cooper Health Sys. v. Virtua Health, Inc.*, 2009 WL 10727982 (D.N.J. July 1, 2009).

The Subpoenas attempt to circumvent the Macro Discovery Order in three key ways. First, the Subpoenas are not limited to documents pertaining to valsartan. The Court's Macro Discovery Order makes clear that, with limited exception, discovery in this litigation should be limited to valsartan and should not extend to other drugs. Dkt. 303 at ¶ 4. Completely disregarding this Court's ruling, the subpoenas seek discovery regarding other angiotensin receptor blocker and other drugs. Specifically, the subpoenas request information related to all products and not limited to valsartan

products. *See, e.g.* Exhibit **A-1** at Schedule A (defining "sartan," ARB," "recalled products," and "Active Pharmaceutical Ingredient.").

Second, the Subpoenas seek documents relating to non-U.S. sales of valsartan and agreements with non-U.S. customers. The Macro Discovery Order restricts discovery related to foreign sales, marketing materials and agreements, except to the extent the materials relate to "unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan." *Id.* at ¶ 8. Completely ignoring this limitation on discovery, Plaintiffs have served or attempted to serve subpoenas on multiple non-U.S. purchasers of the Manufacturer Defendants' valsartan API. *See, e.g.* **Exs. A-59, A-64** (indicating Third Party API customers). These subpoenas seek information beyond the limited exception to the bar on foreign sales documents set out in the Macro Discovery Order. Specifically, these subpoenas seek contracts, supplementation of Drug Master Files, and FDA communications unrelated to impurities in valsartan. *See* **Ex. A-59**, Tiefenbacher Subpoena at 7-9.

Third, the Subpoenas seek testing discovery beyond the limitations set in the Macro Discovery Order. The Macro Discovery Order limits discovery or testing information to tests "that could identify the presence of nitrosamine contamination [and] testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the Valsartan API and Valsartan[.]" Dkt. 303 at ¶ 8. The testing information sought from the third parties exceeds the scope of testing permitted by

the Order. *See, e.g.,* **Ex. A-52** at "Solvent Manufacturing, Recovery, and Recycling" Request 3 ("Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB."). Such requests would only serve to expand the scope of the already-extensive discovery produced in this case[10] into rabbit holes that are not relevant or proportionate to the needs of the litigation.

Plaintiffs should not be permitted to use third party discovery as a vehicle to obtain information that the Court has expressly excluded from the scope of party discovery. For this reason, if all the Subpoenas are not all quashed for the reasons set forth in Section II, the Subpoenas listed in Exhibit B should be quashed in their entirety, as their only purpose is to circumvent the Macro Discovery Order. *See* **Ex. B**, List of Subpoenas to be Quashed. Further, Plaintiffs should be ordered to modify the Subpoenas listed in Exhibit C to preclude the circumvention of the Macro Discovery Order. *See* **Ex. C**, List of Subpoenas to Be Modified.

[10] The Manufacturer Defendants have produced over 4 million pages of documents in response to Plaintiffs' Rule 34 Requests for Production of Documents and the Court's Core Discovery Order (Dkt. 88).

IV. Plaintiffs' Third-Party Subpoenas Undermine the Court's Protective Order

As discussed above, this litigation entails discovery of highly sensitive information, and this Court has entered the agreed Protective Order to governs the production of documents and protect confidentiality concerns. *See* Factual and Procedural Background, Section II, *supra.* The Third Parties are in possession of highly-sensitive commercial and trade secret information regarding defendants that is entitled to protection as "PROTECTED INFORMATION" under the Protective Order. While the Protective Order contemplates third parties disclosing and/or producing "PROTECTED INFORMATION", the Third Parties may be unaware of the protocol contained with it.

Each of the Third Parties may have in their possession documents that are subject to the "Confidential" designation, "Restricted Confidential" designation as outlined in the Protective Order. However, if produced by the Third Parties, Defendants' commercially sensitive and trade secret information may be produced without Defendants having any opportunity to designate sensitive documents so that they may be afforded the confidentiality protections of the Protective Order. Defendants request a protective order affording them 30 days to review the relevant documents, and issue appropriate designations in accordance with the Protective Order prior to Plaintiffs' receipt of the documents.

V. Issues Specific to Each Defendant

A. Subpoenas Served on ZHP-Related Parties Should be Quashed or Modified

Plaintiffs served or attempted to serve twenty-one Subpoenas on Third Parties they represent to have some involvement with one or more of the ZHP Parties. Of the eighteen Subpoenas that remain unmodified, the ZHP Parties request the Court quash eight, and order Plaintiffs to narrow the requests of the remaining ten.

1. The Court Should Quash Subpoenas To ZHP-Related Third Parties That Seek Information Wholly Unrelated to the Subject Matter of the Litigation

The Court should quash the Subpoenas directed to the following Third Parties purportedly connected to the ZHP Parties as listed in **Ex. B**:

1. Azbil Telstar Technologies
2. CABB AG
3. Chemo Group India
4. Linhai Huanan Chemical Co., Ltd.
5. Malvern Instruments
6. Shiva Pharmachen Pvt. Ltd.
7. Tiefenbacher API + Ingredients
8. VXL Life Sciences

a. API Customers and Testing Entities

Many of the Subpoenas issued by Plaintiffs directed to Third Parties purportedly related to the ZHP Parties are directed to non-U.S. purchasers of grade API from the ZHP Parties and entities who conducted particle testing unrelated to identifying nitrosamine impurities. Despite engaging in multiple rounds of meet and

confer sessions, Plaintiffs have been unwilling or unable to provide any basis to expect these Third Parties are likely to possess documents relevant to this litigation.

For example, Plaintiffs issued Subpoenas to Tiefenbacher API + Ingredients, a German entity, and VXL Life Sciences, an Indian company, due to their involvement with API and particle size testing. *See* **Exs. A-59, A-64.** However, these third parties are customers of the ZHP parties who distribute several types of API in foreign markets outside of the U.S. Tiefenbacher is a distributor of API for European markets and VXL is an API distributor for Indian markets. Neither of these companies distribute API in the U.S. nor do they distribute or supply USDMF-grade API. Therefore, they clearly do not possess any relevant documents or information because, to the extent they possess information relating to valsartan, it relates to non-U.S. sales.

Furthermore, Plaintiffs subpoenaed Malvern Instruments, a British entity, and claim that Malvern Instruments performed particle size testing for Valsartan. *See* **Ex. A-35.** Malvern Instruments is one of the largest providers of particle testing equipment in the world. As such, it comes as no surprise to find that the ZHP Parties, as well as many other Defendants, purchased equipment from Malvern Instruments to conduct particle size testing for myriad of substances. However, particle size testing has absolutely no connection to the detection or identification of nitrosamines, carcinogens, or any general toxic impurities at all. Particle size testing

determines the physical size of particles (e.g. microns, millimeters, etc.) and is not a method to detect and identify nitrosamines. Therefore, Malvern Instruments does not possess any relevant documents or information related to the manufacture or distribution of US grade valsartan because its equipment is used to test the size of particles, not their chemical composition. This testing plainly falls outside the parameters on testing discovery laid out in the Macro Discovery Order. *See* Dkt. 303 at ¶ 8 (limiting testing discovery to testing that could identify the presence or nitrosamines, carcinogens, general toxic impurities, and residual solvents).

Moreover, ZHP has been unable to identify any connection to Chemo Group India relating to the manufacturer of U.S grade valsartan API. *See* **Ex. A-15.** Plaintiffs pointed to a single email between ZHP and Chemo Group India's parent company concerning valsartan API, on which Chemo Group India was copied. Plaintiffs have not provided any further evidence to establish any reliable connection between Chemo Group India, which appears to be an Indian subsidiary of a Spanish biotechnology company, and U.S. sales of valsartan, as would be required for the subject matter to fall within the scope of the Macro Discovery Order.

b. Raw Material Suppliers

Plaintiffs also issued Subpoenas to CABB AG, Linhai Huanan Chemical Co., Ltd., and Shiva Pharmacem, three foreign entities who were raw material suppliers. *See* **Exs. A-9, A-34, A-52.** However, the starting ingredients these entities supplied

– valeryl chloride (CABB AG and Shiva) and BBTT (Linhai) – have no impact on the chemical reaction that allegedly could result in the impurity occurrence in valsartan API. Accordingly, they are irrelevant to the claims and defenses in this case and should be quashed.

c. Recall Providers and Consultants

In addition to striking the aforementioned subpoenas, if the Court does not quash all the Subpoenas for the reasons set forth in Section III, this Court should instruct Plaintiffs to narrow their requests and modify the scope of all remaining third-party subpoenas associated with the ZHP Parties to ensure that they comply with the law of the case as outlined in the Macro Discovery Order. Even if the remaining Third Parties possess documents or information relevant to the litigation, the generic and all-encompassing subpoenas that Plaintiffs have served still violate Rule 26(b)(1), which requires that discovery be limited to relevant information and proportionate to the case. The purpose of Rule 26(b)(1) and the Macro Discovery Order is to limit discovery to facts or circumstances relating to the claims or defenses asserted in this litigation, and therefore the subpoenas directed to the Third Parties contained in Ex. C should be modified to eliminate those requests that have nothing to do with that entity's business operations as they relate to the subject matter of this case.

Two intended recipients of Subpoenas–Return Logistics International Corporation and Stericycle Expert Solutions–are recall service providers. *See* **Exs. A-47, A-58.** Notwithstanding their limited involvement with any of the claims or defenses asserted in this litigation, the subpoenas directed to these two entities are overbroad to the extent they seek discovery beyond recall or quarantine and destruction topics. The business operations of these two entities is in no way related to nitrosamine contamination, testing data, or toxicology assessment, and yet, Plaintiffs have included dozens of requests on these topics in the subpoenas. Similarly, another third party – ProPharma Group, Inc. – is a pharmacovigilance consultant that was retained by ZHP to assist with regulatory matters related to the valsartan recall. *See* **Ex. A-44.** Despite this narrow nexus to the subject matter of this case, the subpoena directed to ProPharma seeks discovery on dozens of requests unrelated to the services it provided, including requests for documents related to solvent manufacturing and toxicology assessments.

The flagrant overbreadth of these subpoenas suggests Plaintiffs made no effort to tailor the scope of the subpoenas to the business operations of any of these entities. The subpoenas, thus, seek discovery that is irrelevant and disproportionate and constitute a gross burden on third parties, each of which are the intended recipients of the same or substantially similar subpoenas despite their the obvious and vast businesses differences. Accordingly, the Court should instruct Plaintiffs to narrow

their requests and modify the scope of all remaining third-party subpoenas associated with the ZHP Parties to comply with the Court's macro discovery directives.

B. The Subpoena to Amsal Chem Pvt. Should Be Quashed (Mylan)

Mylan has determined that the subpoena directed to Amsal Chem Pvt. ("Amsal") should be either voluntarily withdrawn by Plaintiffs or quashed because this entity had no involvement in the manufacture of any the valsartan API or finished dose at issue in this litigation. Specifically, although Amsal is an entity with whom Mylan has conducted business, Mylan is not aware of any raw material or ingredient obtained from Amsal that was used to manufacture valsartan API or finished dose marketed or sold by Mylan in the United States. Further, Amsal did not have any other involvement with respect to the valsartan containing medications at issue. Mylan has made this representation to Plaintiffs, and Plaintiffs have not provided any evidence of Amsal's involvement to the contrary. Thus, Plaintiffs' subpoena of Amsal is improper and should be voluntarily withdrawn or quashed.

C. The Subpoenas Served on Meridian Consulting and ToxRox Consulting, LLC Should be Quashed Because They Encompass Documents Protected by the Work Product Doctrine And Attorney-Client Privilege (Aurobindo)

1. Work Product

The work product privilege offers qualified protection from disclosure of documents "prepared in anticipation of litigation rather than in the ordinary course of business." *Miller v. J.B. Hunt Transp., Inc.*, 339 N.J. Super. 144, 148 (N.J. App. Div. 2001). A document is "prepared in anticipation of litigation if the 'dominant purpose' in preparing the document was concern about potential litigation and the anticipation of litigation was 'objectively reasonable.'" *Id.* Notably, a document may "be found to have been prepared in anticipation of litigation even though litigation [has] not been commenced or even threatened when the document was prepared." *Id.* "A document prepared at the direction of an attorney before litigation has commenced may be protected by the work product privilege if its use for litigation was the dominant purpose of preparing the document and if the attorney's belief that litigation would ensue was objectively reasonable." *K.L. v. Evesham Tp. Bd. of Educ.*, 423 N.J. Super 337, 354 (N.J. App. Div. 2011).

a. Consultants Engaged to Assist Outside Counsel in Providing Legal Advice on A Response to an FDA Warning Letter Possess Information Prepared In Anticipation of Litigation and, Thus, Protected by the Work Product Doctrine

The Subpoenas to Meridian and ToxRox should be quashed because all documents in their possession were prepared on behalf of Aurobindo in anticipation of litigation and, therefore, are protected by the Work Product Doctrine. Alternatively, Aurobindo requests entry of a protective order to allow counsel for Aurobindo to review the documents before they are produced to Plaintiffs' counsel.

The work product doctrine encompasses "tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, **consultant**, surety, indemnitor, insurer, or agent)." FED. R. CIV. P. 26(b)(3) (emphasis added); *In re Niaspan Antitrust Litig.*, 2017 WL 3668907, at *2-3 (E.D.P.A. August 24, 2017) (quoting *Martin v. Bally's Park Place Hotel & Casino*, 983 F.2d 1252, 1258 (3d Cir. 1993) ("[A] document satisfies Rule 26(b)(3) where in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation.").

Aurobindo engaged both Meridian and ToxRox to assist its outside counsel in providing legal advice to Aurobindo regarding its response to a regulatory agency's

notification of violations of federal regulations (i.e., an FDA Warning Letter). [11] The anticipation of litigation was objectively reasonable. In fact, this sort of relationship was examined, and the work product privilege was extended to a consulting firm hired by a pharmaceutical company's outside counsel to assist the company in responding to an FDA warning letter. *See Todd v. STARR Surgical Co.*, 2015 WL 13388227, at *3 (C.D. Ca. August 21, 2015) ("The work product privilege of Fed. R. Civ. P. 26(b)(3) applied to information provided by a consultant to assist a law firm in advising a client on how to respond to a federal agency warning letter because the consultant's work was performed in anticipation of future regulatory and legal proceedings, the consultant was hired to aid the firm in understanding the client's regulatory compliance and thereby assisted in the firm's provision of legal advice, and the routine aspects of the consultant's work in helping the client to improve its audit procedures could be viewed as preventing anticipated litigation and did not defeat the privilege"); s*ee also K.L. v. Evesham Tp. Bd. of Educ.*, 423 N.J. Super 337 (N.J. App. Div. 2011) ("A document prepared at the direction of an attorney before litigation has commenced may be protected by the work product privilege if its use for litigation was the dominant purpose of preparing the document and if the **attorney's belief that litigation would ensue was objectively reasonable**")

[11] Outside counsel for Aurobindo at the time was *not* the firm that represents them in this litigation, i.e., Cipriani & Werner, P.C.

(emphasis added); *Miller v. J.B. Hunt Transp., Inc.*, 339 N.J. Super. 144, 150, (N.J. App. Div. 2001) (holding a document is "prepared in anticipation of litigation if the 'dominant purpose' in preparing the document was concern about potential litigation and the anticipation of litigation was 'objectively reasonable.'"). Thus, any documents from Meridian and ToxRox should be protected by the work product doctrine.

The holding in *In re Niaspan Antitrust Litigation* is also instructive here. The litigation involved a motion to compel discovery, *among which* included an email from a consultant, hired by one of the parties to create a compliance report with a co-promotion agreement. *In re Niaspan Antitrust Litig.*, at *12. Based on the compliance report, if the entity was not in compliance, litigation would have ensued. *Id.* Based on this, the court ruled, "the report was therefore prepared in anticipation of litigation, and, **even though "[the compliance report was] prepared by a consultant**, they were properly withheld as work product." *Id.* (emphasis added). In this case, much like *In re Niaspan Antitrust Litigation.,* consultants were hired for the purpose of providing legal advice to the client on preparation of a document regarding regulatory compliance.

For the foregoing reasons, the subpoenas must be quashed, or, alternatively, a Protective Order must be entered wherein Aurobindo is permitted to review the documents and make appropriate disclosures and withholdings based upon the work

product doctrine.

2. Attorney-Client Privilege

Generally speaking, "[c]ommunications between attorney and client are not privileged if made in the presence of or communicated to third parties." *In re Niaspan Antitrust Litig.*, at *2 (quoting *Barr Marine Products, Co. v. Borg-Warner Corp.*, 84 F.R.D. 631, 634 (E.D. Pa. 1979)). Additionally, disclosing such information and communications to a third party waives the privilege. *Id*. However, an exception to this rule exists, wherein, "disclosures made to a third-party consultant do not constitute a waiver when the disclosure is 'necessary for the client to obtain informed legal advice' or if the **disclosure is made "'to an 'agent' assisting the attorney in giving legal advice to the client.**'" *Id.* (quoting *Westinghouse Elec. Corp. v. Republic of Phil.*, 951 F.2d 1414, 1423-24 (3d Cir. 1991); *see also In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 352 F. Supp. 3d 207, 210 (E.D.N.Y. 2019) (quoting *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981)) ("[T]he privilege exists to protect not only the giving of professional advice to those who can act on it but **also the giving of information to the lawyer to enable him to give sound and informed advice**.") (emphasis added).

a. The Privilege Extends To Documents Belonging To Meridian and ToxRox Because Both Consultants Assisted Aurobindo's Outside Counsel In Providing Legal Advice To Aurobindo

The Subpoenas should be quashed because all documents are protected by the attorney-client privilege since both consultants provided information to Aurobindo's outside counsel that was necessary for outside counsel to render legal advice to Aurobindo regarding its response to a Warning Letter from the FDA. Alternatively, Aurobindo requests entry of a protective order to allow counsel for Aurobindo to review the documents before they are produced to Plaintiffs' counsel.

The holding in *In re Niaspan Antitrust Litigation* is also instructive here. There, the Court ruled that information shared with outside counsel for the purpose of providing legal advice with respect to a promotion agreement was protected by the attorney-client privilege. *In re Niaspan Antitrust Litig.*, at *7. This sentiment was echoed in *Federal Trade Commission v. GlaxoSmithkline*, where the D.C. Circuit applied the attorney-client privilege to Glaxosmithkline's documents provided to outside consultants where the consultants were hired "to provide input to the legal department and/or receive the legal advice and strategies formulated by counsel." *See Federal Trade Commission v. GlaxoSmithkline*, 294 F.3d 141, 147 (D.C. Cir. 2002). The D.C. Circuit noted that the consultants hired by Glaxosmithkline were hired to render legal advice. *Id.* at 148.

Here, Aurobindo hired Meridian and ToxRox for the sole purpose of assisting its outside counsel in rendering legal advice to Aurobindo in response to an FDA warning letter. Such relationships and communications have routinely been protected by the attorney-client privilege. *See In re Niaspan Antitrust Litig.*, *2 (refusing to rule that disclosures to third parties hired to assist an attorney to give legal advice break the attorney-client privilege); *see also GlaxoSmithkline*, 294 F.3d at 147 (demonstrating a relationship between an attorney and consulting firm for the purpose of the attorney rendering legal advice is protected by the attorney-client privilege); *In re CV Therapeutics, Inc. Sec. Litig.*, 2006 WL 1699536, at *7 (N.D. Cal. June 16, 2006) (holding the privilege attaches to third party consultants involved in rendering legal advice). Because Meridian and ToxRox were hired to assist Aurobindo's outside counsel in rendering legal advice to Aurobindo, any documents in their possession are shielded by the attorney-client privilege.

For the foregoing reasons, the Subpoenas must be quashed, or, alternatively, a Protective Order must be entered wherein Aurobindo is permitted to review the documents and prepare an appropriate privilege log delineating the documents that are subject to the attorney-client privilege.

D. Teva-Specific Issues

Counsel for the Teva Defendants met and conferred with Plaintiffs' counsel on November 10, 2020, regarding the Third Party Subpoenas purportedly related to Teva. With the exception of two entities which counsel for Teva informed Plaintiffs are in fact Teva predecessor entities/subsidiaries (and would therefore be producing any relevant documents as part of Teva's ongoing document productions), Plaintiffs' counsel was unable to provide any substantive basis for their belief that the other 16 entities would be in possession of documents relevant to Teva and this litigation. Teva explained the contours of the Macro Discovery Order to Plaintiffs' counsel, who was apparently unaware of the order or did not anticipate that Defendants would take the position that the macro discovery limitations applied to such Subpoenas. Faced with this information, Plaintiffs' counsel indicated they would revisit whether to withdraw or modify said subpoenas, but to date Plaintiffs have neither agreed to a single limitation on the number and scope of these subpoenas nor have they provided Teva with any further information to substantiate the claim that these entities may be in possession of relevant information

CONCLUSION

Despite the millions of pages of documents exchanged in the course of discovery, and this Court's clear directives focusing the parties' discovery efforts, Plaintiffs have nevertheless pursued these Third Party Subpoenas and saddled the

Third Parties with onerous and irrelevant document requests. The Subpoenas are not only procedurally defective, which is reason enough for this Court to quash them; they also constitute a brazen attempt by Plaintiffs to seek discovery that this Court has already stated is off-limits and would jeopardize the confidentiality protections in place.

Accordingly, for the reasons stated above, Defendants request the Subpoenas attached at Exhibit A be quashed, and, in the alternative, that the Subpoenas identified at Exhibit B be quashed in their entirety and Plaintiffs be directed to narrow the scope of the Subpoenas identified at Exhibit C.

Respectfully submitted,

By: */s/ Seth A. Goldberg*

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